



# Help Me Quit @ Pharmacy

Smoking Cessation Pharmacy – Level 3 Enhanced Service Specification

This document describes the specification and standards pertaining to the Community Pharmacy Enhanced Service Smoking Cessation. This document does not constitute a service level agreement (SLA) although the provisions within the document will be contained within an SLA between the Local Health Board and pharmacy contractor for the provision of the service.

## INTERPRETATION

In this document:

*Approved service provider (or service provider)* means a registered pharmacist, pre-registration pharmacist, registered pharmacy technician, or other member of healthcare staff, who has completed the relevant training programme(s) via the *National Enhanced Service Accreditation system* and is registered as an approved service provider with NWSSP;

*Local Health Board* means the relevant health board in whose area the service is provided;

*Patient* means any person in receipt of the service;

*Pharmacy* means any premises where drugs are provided by a pharmacist as part of pharmaceutical services.

*Pharmacy contractor (or contractor)* means a person lawfully conducting a retail pharmacy business.

*Registered pharmacist* means a person who is registered in Part 1 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976.

*Registered pharmacy technician* means a person who is registered in Part 2 of the GPhC register.

---

### 1. SERVICE AIM

- 1.1. To provide one to one behavioural support and advice to smokers who are motivated to give up smoking, taking advantage of the accessibility and convenience of community pharmacies.;

### 2. SERVICE OUTCOMES

- 2.1. Improved choice of NHS stop smoking services and increased access to appropriate pharmacotherapy to support quitting;
- 2.2. Reduction in the number of people smoking, through provision of successful smoking cessation support through community pharmacies;
- 2.3. Improved cost-effectiveness of pharmacotherapy provision through targeted, phased supply accompanied by appropriate support and advice;
- 2.4. Reduced smoking cessation related workload in general practice by provision of a service to which patients can be easily referred;
- 2.5. Improved integration of community pharmacy into wider Public Health stop smoking strategy.

### 3. PATIENT ELIGIBILITY

- 3.1. A person may access the service if at its commencement they are a smoker or are within 4 weeks of the start of their quit attempt.
- 3.2. A person may access the service following a referral from a healthcare professional or another Help Me Quit (HMQ) provider, including transfer of care, or may refer himself or herself directly.
- 3.3. The service will be provided to people who live, or are registered with a GP, in Wales.
- 3.4. A person wishing to use the service must consent to the sharing of information about their quit attempt with the person with whom they are registered for the provision of General Medical Services and with NHS Wales for the purposes of post payment verification.
- 3.5. Subject to paragraphs 3.6 and 3.7 the service will be provided to any person aged 18 years or older.
- 3.6. The service may be provided to any person aged between 12 and 17 years provided that
  - 3.6.1. The approved service provider undertakes an assessment of their competence and on completing that assessment considers them to be competent to consent to treatment; and
  - 3.6.2. The approved service provider provides them with information regarding smoking cessation by children and young people.
- 3.7. The service may be provided to individuals with co-morbidities, or women who are breastfeeding, where they are provided with relevant information regarding smoking cessation for people with their condition. Where pharmacotherapy is provided as part of the service, the responsible pharmacist must consider that it is safe to do so and that such use is within the terms of its summary of product characteristics.
- 3.8. The service may be provided to women who are pregnant. In the first instance, they should be offered behavioural support only. If this fails, or it is reasonable to assume it will not be successful, they may be offered behavioural support with supply of Nicotine Replacement Therapy.
- 3.9. The service will **only** be provided to any person who has made an unsuccessful quit attempt in the previous six months in exceptional circumstances, which are at the discretion of the approved service provider.

### 4. SERVICE DESCRIPTION

- 4.1. The service provider shall provide the service in a manner that is user-friendly, non-judgmental, patient-centred, and confidential.
- 4.2. Subject to paragraphs 4.11.1 and 4.11.2, following each consultation, the approved service provider may supply appropriate pharmacotherapy in support of a quit attempt.
- 4.3. At each consultation, the service provider will provide appropriate resources to support quit attempts. The LHB may mandate particular resources be used by providers.

- 4.4. When a patient leaves the service the approved service provider will provide the patient's GP with confirmation that the patient has accessed the service, of the patient's 4 week quit status (if available) and of the stage at which the patient left the service.
- 4.5. A claim must be entered into the relevant section of the National Electronic Claim and Audit Form (NECAF) or any subsequent national claim and audit process to ensure effective ongoing service delivery and audit. Except in exceptional circumstances, information will be provided no more than 4 weeks following the patient leaving the service to enable the local health board to monitor the service effectively.
- 4.6. *Standards for Initial contact and assessment ("pre-quit attempt")*
  - 4.6.1. On presentation of a person seeking help to stop smoking the service provider shall:
    - 4.6.1.1. Assess the patient's eligibility to access the service, as set out above;
    - 4.6.1.2. Provide information regarding the range of HMQ services available to support the person to stop smoking (unless this has already been provided recently e.g. by the HMQ contact centre);
    - 4.6.1.3. Make an initial assessment of the patient's motivation. Patients who require additional support that cannot be provided in the community pharmacy should be signposted to the Help Me Quit contact centre, or another appropriate HMQ service available locally;
    - 4.6.1.4. Explain the HMQ pharmacy service and provide any support materials that have been made available by the Local Health Board or Public Health Wales, including a *patient record form* to be returned to the pharmacy at consultation one; and
    - 4.6.1.5. Agree a convenient date with the patient, which would normally be within the following two weeks, for consultation one according to the following principals:
      - 4.6.1.5.1. Where a patient has been referred to the service from another HMQ service provider and an initial discussion has already taken place, consultation one may take place without a pre-quit attempt assessment. Where there has been a significant gap between the patient accessing the HMQ service and attending the pharmacy, the service provider should reassess motivation to quit and agree the consultation one date accordingly.
      - 4.6.1.5.2. Where a patient has not been referred from another HMQ service, the service provider will assess the patient's motivation to quit.
      - 4.6.1.5.3. If the pharmacy is unable to provide a mutually convenient appointment within a reasonable period, the patient should be referred to another HMQ service provider.

4.7. All consultations shall be conducted by an approved service provider who meets the requirements set out in paragraphs 5.14 and 5.15. The approved service provider will complete the below steps at each relevant consultation (as defined in the Minimum Service Standards for Help Me Quit Services):

4.8. Consultation *one (week 0)*

4.8.1. Greet smoker with name and check patient's name

4.8.2. Check that smoker is seeking help with stopping smoking

4.8.3. Obtain their consent and, if necessary, assess and record competence to consent;

4.8.4. Explain what will happen in the rest of the session

4.8.5. Explain what the course involves, the benefits and what is required of the patient

4.8.6. Check that the patient wishes to proceed and set a quit date within the next two weeks

4.8.7. Provide, and explain the use of, a Passport to Smokefree

4.8.8. Set a definite quit date and record in Passport to Smokefree

4.8.9. Measure expired-air CO and discuss the reading, explaining how it will return to normal after just one day of not smoking

4.8.10. Explain medication options, benefits and side effects

4.8.11. Get smoker to decide on medication option and record in Passport to Smokefree

4.8.12. Explain optimum use of the chosen medication if one is chosen

4.8.13. Explain the importance of the 'not a puff' rule and the reason for it

4.8.14. Explain the importance of avoiding smoking triggers and why and get patient to commit to one or more ways of reducing exposure to triggers, including changing routines

4.8.15. Explain the importance of doing something active to reduce and cope with cravings when these occur and get commitment to use at least one of the evidence-based approaches (breathing exercises, physical activity, isometric exercises)

4.8.16. Explain the importance of starting to think like a non-smoker and commit every day to the not-a-puff rule for that day

4.8.17. Check that the patient understands items 4.8.1 to 4.8.16 and ask patient if they have any queries or concerns and address these

4.8.18. Schedule remaining sessions if possible and at least the next session

4.8.19. Sign off with a motivational message

- 4.8.20. Create an individual patient record using NECAF or any such system as it is replaced by
- 4.8.21. Where requested by the patient supply appropriate pharmacotherapy in accordance with paragraphs 4.11.1 and 4.11.2 of this document.

4.9. Consultations *two, three, four, and five (1, 2, 3, and 4 weeks after quit date respectively) and six, seven and eight (to be carried out at intervals of approximately two weeks)*

4.9.1. Greet patient

4.9.2. Ask about abstinence status using standardised language

4.9.3. Measure expired-air CO and discuss the reading

4.9.4. If abstinent:

- 4.9.4.1. Congratulate
- 4.9.4.2. Ask about medication adherence and side effects and address issues
- 4.9.4.3. Ask about use of Passport to Smokefree and address issues
- 4.9.4.4. Discuss challenges and solutions for coming week
- 4.9.4.5. Confirm arrangements for next session
- 4.9.4.6. Sign off with a motivational message; reinforce 'not-a-puff' rule

4.9.5. If not abstinent:

4.9.5.1. Provide motivational boost and ask if continuing with quit attempt

4.9.5.2. If **not** planning to continue with quit attempt, provide supportive message and discuss intention to try again in a few months

4.9.5.3. If **is** planning to continue with quit attempt:

- 4.9.5.3.1. Congratulate and stress importance of recommitment
- 4.9.5.3.2. Ask about medication adherence and side effects and address issues; advise on increasing NRT use if appropriate
- 4.9.5.3.3. Ask about use of Passport to Smokefree and address issues
- 4.9.5.3.4. Discuss challenges and solutions for coming week
- 4.9.5.3.5. Confirm arrangements for next session
- 4.9.5.3.6. Sign off with a motivational message
- 4.9.5.3.7. Where a service user is continuing to smoke over multiple consultations the service provider should discuss the value of continuing the attempt and consider a potential exit of the service until such time as the smoker is ready to attempt to quit again

4.9.6. Arrange supply of pharmacotherapy as appropriate (see paragraph 4.11);

4.9.7. Record details on NECAF or any such system as it is replaced by

4.10. *Assessing quit status*

4.10.1. The approved service provider will establish and record the CO validated quit status of each patient at each consultation; (note that a validated quit is a CO reading of less than 10 ppm or a green or orange light on the Compact smokelyzer®);

- 4.10.2. The approved service provider will contact patients that are no longer engaging with the service (e.g. by telephone) to establish their self-reported quit status;
- 4.10.3. The approved service provider will inform the patient that they may be contacted regarding their smoking status at 52 weeks following their quit date, and that they may be asked to attend the pharmacy to verify their smoking status by CO monitor.
- 4.10.4. Where requested to do so by the Local Health Board the approved service provider will facilitate patients' participation in any survey designed to measure the quality of the pharmacy service or stop smoking services more generally (e.g. by providing them with a questionnaire).

#### 4.11. *Supply of pharmacotherapy*

- 4.11.1. Where the approved service provider is a registered pharmacist they may:
  - 4.11.1.1. Supply GSL or P classified pharmacotherapy licensed for use in the UK; or
  - 4.11.1.2. Where a Patient Group Direction (PGD) is in place within the area of the Local Health Board in which the pharmacy is located, supply a prescription only medicine product, authorised for supply under that PGD<sup>1</sup>;
- 4.11.2. Where the approved service provider is **not** a registered pharmacist, they may either:
  - 4.11.2.1. Supply GSL or P classified pharmacotherapy licensed for use in the UK, under the supervision of a registered pharmacist; or
  - 4.11.2.2. Refer the patient to a registered pharmacist at the pharmacy who is also an approved service provider and who may then act in accordance with the requirements of paragraph 4.11.1.
- 4.11.3. All supplies of pharmacotherapy shall be as part of an NHS Wales service and shall be made at no cost to patients.
- 4.11.4. Subject to paragraphs 4.11.1 and 4.11.2, approved service provider may supply appropriate pharmacotherapy in support of a quit attempt. In doing so all supplies of pharmacotherapy must be:
  - 4.11.4.1. Made by or under the supervision of a registered pharmacist; and

---

<sup>1</sup> Each Local Health Board may provide patient group directions (PGD) to be used by registered pharmacists providing the service in their area. These PGDs are specific to each LHB and a registered pharmacist may only provide a medicine under a PGD from a pharmacy in an LHB where a PGD is in place and they have signed a current copy.

- 4.11.4.2. Made in accordance with the relevant product’s marketing authorisation; or
  - 4.11.4.3. Made in accordance with any patient group direction that is in operation within the Local Health Board;
  - 4.11.4.4. Cognisant of relevant national or local guidance and the relevant prescribing policies and guidance in use in each Local Health Board area so far as these relate to pharmacotherapy used to support people who wish to stop smoking; and
  - 4.11.4.5. In cases where NRT dual therapy is to be supplied, it must comprise not more than one long acting NRT formulation (e.g. patch) and not more than one short acting NRT formulation (e.g. gum) in any single consultation.
- 4.11.5. Any pharmacotherapy must be supplied in its original pack and be marked indelibly “NHS” to reduce the potential for fraud. All products supplied must be labelled as if they were dispensed medicines. Products supplied under PGD must also be labelled in accordance with the labelling requirements set out in the Medicines Act 1968.
- 4.11.6. A patient may receive a maximum of 12 weeks supply of pharmacotherapy per quit attempt and supplies will be made according to the following schedule:

<b>Consultation</b>		<b>NRT supply:</b>	<b>Varenicline supply:</b>
<b>1</b>	week 0	1 week	2 weeks
<b>2</b>	1 week after quit date	1 week	Consultation only
<b>3</b>	2 weeks after quit date	1 week	2 weeks
<b>4</b>	3 weeks after quit date	1 week	Consultation only
<b>5</b>	4 weeks after quit date	2 weeks	2 weeks
<b>6</b>	6 weeks after quit date	2 weeks	2 weeks
<b>7</b>	8 weeks after quit date	2 weeks	2 weeks
<b>8</b>	10 weeks after quit date	2 weeks	2 weeks

4.12. Where a patient fails to attend ‘consultation only’ sessions, the service provider will reassess motivation to quit and engagement with the service. Where the service provider considers that the patient is not motivated to quit and/or is not engaged with the service, they may stop the service and recommend that the patient return to make a new quit attempt later.



## **5. PROVIDER RESPONSIBILITIES**

### *Contractors*

- 5.1. Contractors wishing to provide the service will apply to their Local Health Board using the form required by their LHB;
- 5.2. Other than with the agreement of their Local Health Board, the contractor will ensure that the service is only provided from an area of the pharmacy which;
  - 5.2.1. Must be a designated area which is distinct from the general public areas of the pharmacy; and
  - 5.2.2. Must be an area where both the patient receiving the service and the registered pharmacist talk at normal speaking volumes without being overheard by other visitors to the pharmacy.
- 5.3. The contractor will ensure that appropriate indemnity arrangements are in place for registered pharmacists, registered pharmacy technicians and other staff involved in providing the service;
- 5.4. The contractor will ensure that a functioning CO monitor, and appropriate mouthpieces, are available for use by approved service providers;
- 5.5. Any staff who are not approved providers, but are involved in elements of service delivery, will be fully informed and suitably trained in relation to their involvement in the service. This may include the provision of any part of the service provided on behalf of an approved service provider, if they are competent and it is legal for them to do so. For the purpose of this agreement, staff will include any person or persons employed or engaged by the contractor, to provide any part of the service;
- 5.6. The contractor will have awareness of, and ensure the service is provided in accordance with, any relevant nationally or locally agreed standards;
- 5.7. The contractor will ensure that all standards required by the General Pharmaceutical Council, so far as they relate to pharmacy owners and superintendent pharmacists, are met;
- 5.8. The contractor will ensure that, prior to entering into any agreement to provide the service; they are satisfactorily complying with their obligation under Schedule 2 to the Pharmaceutical Services Regulations to provide pharmaceutical essential services and have a system of clinical governance that is acceptable;
- 5.9. The contractor will have appropriate arrangements in place to maintain service continuity and take all reasonable steps to ensure that patients are able to access this or equivalent services in the event of unforeseen closure of the pharmacy
- 5.10. The contractor will notify the relevant Local Health Board, of circumstances which result in the temporary unavailability of the service for more than 14 calendar days;
- 5.11. The contractor will participate in any reasonable publicity of the availability of the service required by the Local Health Board and shall only publicise the availability of the service using HMQ approved materials, unless otherwise agreed by the Local Health Board;

- 5.12. The contractor will participate in any reasonable review of the service required by the Local Health Board including the reporting of any incidents to the Medical Director of the relevant Local Health Board.
- 5.13. The contractor will ensure that the service is provided by approved service providers who are able to demonstrate competence according to the provisions set out in paragraphs 5.14 and 5.15 and have their names included in the All Wales Pharmacy Database, or other relevant list for other staff, for the service.

#### *Accreditation requirements*

- 5.14. Registered pharmacists, pre-registration pharmacists and registered pharmacy technicians wishing to provide the service will:
  - 5.14.1. Complete the Stop Smoking module in the National Enhanced Services Accreditation Hub – the results of which will be forwarded to NWSSP
  - 5.14.2. Have successfully completed an enhanced Disclosure and Barring Service (DBS) check request with NWSSP.
  - 5.14.3. For pharmacists providing varenicline under a PGD, have supplied a signed copy of the PGD to NWSSP for each of the LHBs in which they will be providing varenicline under this service
- 5.15. Other members of staff, engaged by a commissioned pharmacy contractor, who wish to provide the service will:
  - 5.15.1. Complete the Generic Skills requirements of the National Enhanced Services Accreditation Hub – the results of which will be forwarded to NWSSP
  - 5.15.2. Complete the Stop Smoking module in the National Enhanced Services Accreditation Hub – the results of which will be forwarded to NWSSP
  - 5.15.3. Have completed training as a medicines counter assistant, meeting the requirements of the General Pharmaceutical Council, and provide appropriate certificates demonstrating this to NWSSP
  - 5.15.4. Have successfully completed an enhanced Disclosure and Barring Service (DBS) check request with NWSSP; and
  - 5.15.5. Have their names included in the All Wales Pharmacy Database (or other relevant database) for the service.
- 5.16. Approved service providers that are pharmacists shall have familiarised themselves with, and signed, any PGD(s) that are operated by the Local Health Board and relevant to providing this service. A PGD may only be used by an approved service provider who is also a pharmacist and where they are competent to do so and the legal requirements for its use have been satisfied.
- 5.17. Approved service providers shall have an awareness of, and ensure that their practice is in line with, relevant prescribing policies and guidance in use in each LHB area in which they

provide the service so far as these relate to pharmacotherapy used to support people who wish to stop smoking;

- 5.18. Approved service providers shall ensure that their practice complies with all relevant standards required by the General Pharmaceutical Council, as far as they relate to pharmacists and pharmacy technicians.
- 5.19. Approved service providers will be aware of other Help Me Quit services available in the area(s) in which they practice and be able to refer patients to these as appropriate to the needs of the patient.

## **6. LOCAL HEALTH BOARD RESPONSIBILITIES**

- 6.1. The Local Health Board, or their authorised officer, shall determine the fees and allowances payable in respect of the service;
- 6.2. The Local Health Board shall enter into a Service Level Agreement (SLA) with all pharmacies commissioned to provide the service;
- 6.3. The Local Health Board will have in place reasonable measures to ensure that other pharmacies and stakeholders are aware of local service provision;
- 6.4. The Local Health Board, or its authorised officer, shall ensure that procedures are in place to facilitate effective communication and referral between providers and appropriate local NHS services;
- 6.5. The Local Health Board, or its authorised officer, shall support the resolution of difficulties so far as they relate to issues within the control of the Local Health Board;
- 6.6. The Local Health Board, or its authorised officer, shall support the handling of any complaints or issues relating to the service as far as they relate to issues within the control of the Local Health Board.

## **7. WELSH GOVERNMENT RESPONSIBILITIES**

- 7.1. The Welsh Government shall make provision for the NECAF or any replacement mechanism to be available to each pharmacy providing the service;
- 7.2. The Welsh Government shall make provision for the details of each pharmacy providing the service to be included in the All Wales Pharmacy Database;
- 7.3. The Welsh Government shall make provision for the details of each approved service provider to be included in the All Wales Pharmacy Database and shall ensure reasonable access for contractors wishing to verify their accreditation;
- 7.4. The Welsh Government shall make provision for an appropriate level of service performance information to be available to, the contractor, Local Health Boards and other organisations of NHS Wales (e.g. Public Health Wales NHS Trust), and to Community Pharmacy Wales;

## **8. CONFIDENTIALITY AND DATA PROTECTION**

- 8.1. The Service Provider will ensure that no one, whether during or after their appointment, will disclose or allow to be disclosed to any person (except on a confidential basis to their professional advisers) any information of a confidential nature acquired by the Service Provider or any other member of staff involved in delivery of the service in the course of carrying out their duties under this Agreement, except as may be required by law.
- 8.2. The Provider must protect personal data in accordance with the provisions and principles of all extant data protection and confidentiality legislation and regulations and the Confidentiality: NHS Wales Code of Practice, and must ensure that all staff that have access to such data are informed of, and comply with this requirement.
- 8.3. The Provider shall at all times ensure that appropriate technical and organizational security measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
- 8.4. The Provider must be aware that the any information held by the Welsh Assembly Government, Local Health Boards or their authorised officers, may be subject to disclosure under the Freedom of Information Act.
- 8.5. In-pharmacy records relating to provision of this service should be retained in the pharmacy in line with the guidance published at: <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016>

## **9. AUTHORISED OFFICERS**

- 9.1. For the purpose of the service, the Welsh Government and Local Health Boards shall inform the provider immediately, in writing, of the details of any officer authorised to act on its behalf. Any notice, information, or communication given by the authorised officer will be deemed to have been given by the Welsh Assembly Government or Local Health Board as the case may be.

## **10. REVIEW VARIATION AND TERMINATION**

- 10.1. Variation to the service specification can only be made following consultation with Community Pharmacy Wales.
- 10.2. Contractors will be notified of any variations to the service specification in writing. No variation to the specification will be made until 90 days after that notice is received.
- 10.3. Providers, as signatories to the SLA, may cease to provide the service by giving notice in writing to the Local Health Board. In the event of such notice, the service will be terminated 90 days after that notice is received.
- 10.4. The Local Health Board may terminate commissioning of the service by a given provider or providers through given 90 days' notice in writing.
- 10.5. Where a contractor has significantly, or repeatedly, failed to provide the service according to the above provisions, or there is significant concern regarding patient safety, the Local

Health Board may terminate commissioning of the service by that provider with immediate effect.

## **11. FEES AND ALLOWANCES**

- 11.1. Contractors will be reimbursed for any product supplied in accordance with the price set out in Part VIIIA of the Drug Tariff or the manufacturer's list price plus VAT and pursuant to Part I clause 5B(1).
- 11.2. Contractors shall submit all claims using the NECAF or any replacement mechanism that is made available to each pharmacy providing the service.
- 11.3. Claims should ideally be submitted within 4 weeks of patients completing the service, but must be made no later than the 5<sup>th</sup> May following the end of the relevant financial year. Claims made after this date will not normally be paid.
- 11.4. Fees and allowances shall be paid monthly in arrears at the relevant fee level, as published in the Drug Tariff;
- 11.5. Claims for payment shall be subject to post payment verification by the Local Health Board or their authorised representatives.